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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,568	04/12/2004	Thunder Jalili	21101.0136U2	2642

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,568	JALILI, THUNDER	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-12 and 14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-12, 14-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/23/2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-12, 14-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were amended on 4/9/2008 to indicate that the nutritional supplement is administered to the subject for at least seven days prior to the onset of hypertension. However, paragraphs 45 and 47 of example I fails to support this amendment. Example I discloses rats which are surgically altered on the eighth day after feeding the nutritional supplement for seven days exactly. As such, the disease of hypertension is not disclosed in Example I much less the prevention, delaying the onset or slowing the progression of the disease of hypertension and there is no disclosure of a range of days of at least seven days. The only way to know that at least seven days had passed would be to purposely induce the

disease of hypertension such that the person developed hypertension at least by day 8 after seven days of administration. Examples VII and VIII do not address the problem as the time of hypertension is not specifically set, i.e. hypertension occurs at about 5-6 weeks. As such, there is no disclosure that there was prevention of hypertension much less prevention that occurred at least seven days after administration. The above excludes the possibility of prevention since the disease was not prevented and it is not known whether the disease would have been delayed or slowed as one is actively trying to cause the disease of hypertension. In any case, since the purpose of the invention is to prevent, delay the onset or slow the progression of the disease of hypertension, certainly the inventors would not have contemplated an invention where the disease of hypertension is purposely induced after administration of nutritional supplement for seven days.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons above and the further reasons below.

The Applicant argues that the claims do not set forth a range. However, this is argument without merit. The recitation of "at least seven days" constitutes a range, i.e. an open-ended range. See e.g. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range).

Claims 1-8, 10-12, 14-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delaying the onset or slowing the progression of hypertension in a subject, does not reasonably provide enablement for prevention of the

hypertension by administration of quercetin to a subject for at least seven days prior to the onset of hypertension where the hypertension is not surgically induced or the day of onset of hypertension is not otherwise known. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to the prevention, delaying or slowing the progression of hypertension with quercetin.

The state of the prior art and the predictability or lack thereof in the art:

The prior art, as indicated in the prior art rejections below, disclose the delaying and slowing of the progression of hypertension with quercetin but the prior art does not provide evidence of prevention. Further, the prior art does not provide any disclosure as to how one of ordinary skill in the art would be able to predict the day of on which the onset of hypertension occurs such that one of ordinary skill in the art would administer a nutritional supplement as least seven days prior to day absent surgically inducing the same on a specific day. Further, in a later study in which the inventor was one of the authors, it was determined that a quercetin supplemented diet did not prevent cardiovascular complications in spontaneously hypertensive rats, i.e. hypertension was not prevented or delayed (Carlstrom et al., Abstract). Carlstrom et al. disclosed that the method of administration was critical to the effectiveness of quercetin in reducing blood pressure, i.e oral gavage was effective in reducing blood pressure but not dietary supplemented quercetin (Carlstrom et al., page 632). Further, Carlstrom et al. disclose that abdominal aortic constriction (AAC) rats only produced local mechanical hindrance as opposed to systemic hypertension (Carlstrom et al., page 632). As such, predictability with respect to

prevention of hypertension by administering quercetin at least seven days prior to onset hypertension where hypertension is not surgically induced or the day of onset of hypertension is not otherwise known is low.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification provides examples of delaying and slowing of the progression of hypertension with quercetin but the examples show that hypertension was not prevented (Specification, paragraphs 0069-0072).

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that they claim prevention of hypertension with quercetin, however, Applicant's Specification discloses an example that shows that hypertension was not prevented. The scope of the term "prevention" is such that administration of quercetin will prevent hypertension over the life time of the subject. Further, there is no evidence that one of ordinary skill in the art can predict the day when hypertension will occur. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine whether administration of quercetin can prevent hypertension and how one would be able to administer quercetin at least seven days prior to hypertension onset where the hypertension is not surgically induced or the day of onset of hypertension is not otherwise known.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant argues that it has enabled prevention of hypertension. However, contrary to Applicant's arguments, the Specification supports the conclusion that prevention of hypertension is not enabled. SH rats are disclosed to be a model of hypertension resulting from

aging with beginning at 5-6 weeks with peak blood pressure at about 12-15 weeks of age (Paragraphs 0066, 0069). As such, in paragraph 0072, the dietary supplement was initiated at 5 weeks and at week 17 there was no difference between control and quercetin treated rats, as such, it can be concluded that the quercetin failed to prevent hypertension. The Applicant argues that the data shows that the rats were not hypertensive at six weeks post-birth. However, this does not prove prevention as indicated above in rats tested at week 17 there was no difference between control and quercetin treated rats. Further, the Applicant has not shown that the same definition applies to rats which do not have the disease of hypertension but are surgically altered. Furthermore by terms of the claim, hypertension actually occurs, as such, by definition, there can be no prevention. With respect Akt activation and ERK1/2, the same still do not show prevention of hypertension as the rats still showed at least some hypertrophy in Example I.

The Applicant argues that the present claims do not rely on feed supplied supplements. However, claims 18-25 do not exclude non-food dietary supplements. Furthermore, there is nothing in Carlstrom et al. which supports the conclusion that quercetin prevents hypertension as Carlstrom et al. does not indicate that a previous oral gavage study prevented hypertension and indicates that the Abdominal aortic constriction model which is local does not appear to correlate to hypertension which is systemic (Carlstrom et al. at page 632).

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 11, 2009

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616